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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/875,823 | 06/05/2001 | John C. Hiserodt | IRVN001DIV2 | 8672 |

24353 7590 08/24/2004

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EXAMINER

YAEN, CHRISTOPHER H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/875,823 | HISERODT ET AL. | |
| | Examiner | Art Unit | |
| | Christopher H Yaen | 1642 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-79 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-40, 46-48, 52, 54-60, 63-67, 69, 70, 74, 75 and 77-79 is/are rejected.
- 7) ☒ Claim(s) 41-45, 49-51, 53, 61, 62, 68, 71-73 and 76 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Hiserodt *et al*
Priority Date: 25 July 1996

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/2/2004 has been entered.
2. Claims 1-30 are canceled without prejudice or disclaimer, claim 79 is newly added.
3. Claims 31-79 are pending and examined on the merits.

Claim Rejections Maintained - 35 USC § 102

4. The rejection of claims 31-33,35-36,38,40,46-50,52-60,63-65,67,69,72-73, 75-78 and now newly added claim 79 under 35 USC 102(a) as being anticipated by Jadus *et al* (Blood 1996 June;87(12):5232-5241) is maintained for the reasons of record. Applicant's submission for RCE was not accompanied with any additional remarks or arguments concerning the non-anticipatory teachings of Jadus *et al* nor was there any response to the Final Office action mailed 6/3/2003 that were deemed persuasive to overcome the rejections of record. Thus the rejection under 35 USC 102(b) is maintained for the reasons of record.

Claim Rejections Maintained - 35 USC § 103

5. The rejection of claims claims 31-33, 36,38,40,46-50,52-60,63-65,67,69,72-73, 75-78 and now newly added claim 79 under 35 USC 103(a) as being obvious over Jadus *et al* (Blood 1996 June;87(12):5232-5241) is maintained for the reasons of record. Applicant's submission

for RCE was not accompanied with any additional remarks or arguments concerning the non-obviousness of *Jadus et al*, nor was there any response to the Final Office action mailed 6/3/2003 that were deemed persuasive to overcome the rejections of record. Thus the rejection under 35 USC 103(a) is maintained for the reasons of record.

New Arguments

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 31-34,35-36,38,40,46-50,52-60,63-65,67,69,72-73, and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura *et al* (Exp Hematol 1996 Feb;24(2):360-3) in view of Dick JE *et al* (Cancer Surv. 1992;15:161-81.).

a. Kimura *et al* (Exp Hematol 1996 Feb;24(2):360-3) teach a method of treating cancer comprising the administration of a composition for in vivo use (i.e. a pharmaceutical composition) that comprises a cell that expresses a cytokine from a recombinant source and a pharmaceutical excipient, wherein the cytokine is associated with the cell outer membrane. It is further taught that the cytokine is M-CSF, and that the cell expressing the said cytokine is a cancer cell. Because the cell expressing the cytokine is a cancer cell, it inherently possesses tumor associated antigens. Further, it is well known in the art that M-CSF is both naturally membrane associated and soluble (i.e. secreted) (as evidenced by Cosman *et al* (Behring. Inst. Mitt. 1988 August; (83):15-26)), therefore, the cancer cell that express the said cytokine is capable of expressing both

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membrane bound and secreted forms of the cytokine. And lastly, Kimura *et al* also teach that upon re-challenge, tumor cells not expressing the recombinant M-CSF were eradicated based on immune protection (see abstract). Thus claims that read on stimulating an immune response are taught by Kimura *et al*.

b. Kimura *et al* however, do not specifically teach that the subject is a human or that human cells are to be used.

c. Dick JE *et al* (Cancer Surv. 1992;(15):161-81) teach that murine models are relatively predictive or can be correlative to clinical outcome (see abstract).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to treat human subjects with cancer comprising a method of administering a pharmaceutical composition comprising a human cancer cell expressing a recombinant cytokine that is membrane associated for the treatment of neoplastic disease. One of skill in the art would have been motivated to do so because Kimura *et al* taught all the limitations of claims and its effectiveness in a murine model of neoplastic disease. Because Dick *et al* taught that the murine models for cancer are predictive and correlative to clinical outcomes, one of skill in the art would have made the transition from mouse cells to human cells, because ultimately, the study of disease in animal models is to provide clinical outcomes and effective treatment options in humans. One of skill in the art would have expected a reasonable amount of success in making these changes because of the predictable success provided in Kimura *et al* in increasing the survival rate and immune protective effects of the cancer cell expressing the membrane associated cytokine in the treatment of cancer.

Conclusion

8. No claim is allowed.
9. Claims 35,41-45,50-51,53,61-62,68,71-72,73, and 76 are objected to for depending on rejected claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
August 18, 2004



**GARY NICKOL
PRIMARY EXAMINER**